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09/735,638	12/14/2000	Olivier De La Charriere	016800-429	6191

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Norman H. Stepno  
BURNS, DOANE, SWECKER & MATHIS, L.L.P.  
P.O. Box 1404  
Alexandria, VA 22313-1404

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



### DETAILED ACTION

The RCE dated 4-6-06 is acknowledged.

Claims included in the prosecution are 26, 28-50, 53-54, 116 and 121.

#### *Claim Rejections - 35 U.S.C. § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 26, 28, 32-34, 45-46, 116 and 121 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/14084.

Instant claims are drawn to a method of treatment of a sensitive skin wherein substance P has already been released due to the exposure to and contact with one substance P release active agent.

WO teaches a method of treatment of skin by the topical application of the claimed P antagonists for the treatment of diseases such as pruritus and urticaria. The compositions are in the form of ointments, creams, lotions and various other forms and contain other additives and therapeutic agents. (note the abstract, page 5, lines 19-20,

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pages 12-14 and claims). Since WO teaches the application of a substance P antagonist and since the function of an antagonist is to nullify the action of the agent against which it has the antagonist action, the reference reads on instant claims.

Applicant's arguments and the declaration submitted have been fully considered, but are not found to be persuasive. Applicant argues that WO is directed to an allergic condition and it does not disclose or fairly suggest a cosmetic or dermatological method for treating sensitive skin of an individual in need of such treatment, where in the sensitive skin has an amount of substance P already released therein. Applicant further argues that WO relates to the use of piperidine derivatives, showing substance P antagonistic activity, for analgesic or anti-inflammatory properties in the treatment of pathological disorders. Applicant argues based on the declaration submitted that sensitive skin different from allergic skin and that the treatment of pathological disorder showing inflammatory conditions is not sufficient to anticipate or render obvious the claimed methods directed to treating the non-pathological condition of sensitive skin. These arguments are not persuasive since WO teaches skin disorders such as psoriasis, pruritis and sunburn on page 5, lines 19-20 besides the inflammatory conditions and allergic conditions. According to instant claims, the symptoms include discomfort, prickly and erythema. As pointed out before, this means that the substance P is already released in the diseases taught by WO since without such release of substance P, the disease conditions would have manifested. Applicant has not shown that the skin conditions taught by WO do not include the diseases manifested by sensitive skin.

*Claim Rejections - 35 U.S.C. § 103*

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 26, 28-50, 53-54, 116 and 121 are rejected under 35 U.S.C. § 103 as being unpatentable over WO 93/14084.

As pointed out above, this publication teaches a method of treatment of skin by the topical application of the claimed P antagonists for the treatment of diseases such as pruritus and urticaria. The compositions can be in the form of ointments, creams, lotions and various other forms and contain other additives and therapeutic agents. (note the abstract, page 5, lines 19-20, pages 13-14 and claims). WO does not provide any specific examples for the topical application to the sensitive skin wherein the substance P is already released. However, based on the teachings of WO it would have been obvious to one of ordinary skill in the art to use the substance P antagonists taught by WO to counter the irritant side effects of a substance in the cosmetic composition due to the release of substance P since the antagonists counter the substance P. Furthermore, since the function of a substance P antagonist is to antagonize the action of released substance P and nullify its effects and it would have been obvious to one of ordinary skill in the art at the time the invention was made that it

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would nullify the effects of substance P irrespective of whether the substance P is released from a sensitive skin or allergic skin or skin in a inflammatory state.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again pertain to the already released substance P. The examiner has already addressed this issue above. Applicant further argues that the rejection over WO 084 does not give full consideration to all of the claim elements and that patentable weight must be given to "having such amount of substance P already released therein, " and "by exposure to and contact with at least one substance P antagonist effective to reduce or eliminate such amount of said already released substance P". These arguments are not persuasive. With regard to the first point, that is, "having such amount of substance P already released therein, as already pointed out above, the disease conditions would not have manifested in a subject if the substance P has not been released. With regard to the second issue, that is, "by exposure to and contact with at least one substance P antagonist effective to reduce or eliminate such amount of said already released substance P", the examiner points out that WO teaches the application of substance P antagonist to the skin of the subjects who show these conditions and it would have been obvious to one of ordinary skill in the art that the amount of a therapeutic agent would depend upon the conditions of the manifested conditions. Since the severity of the condition depends upon the released substance P, it would have been obvious to one of ordinary skill in the art that the therapeutic amounts taught by WO would be proportional to the substance P released. Finally, the examiner points out that the function of a substance P antagonist

is to antagonize the action of released substance P and nullify its effects and it would have been obvious to one of ordinary skill in the art at the time the invention was made that it would nullify the effects of substance P irrespective of whether the substance P is released from a sensitive skin or allergic skin or skin in a inflammatory state.

5. Claims 26, 28-50, 53-54, 116 and 121 are rejected under 35 U.S.C. § 103 as being unpatentable over Wallengren (contact Dermatitis), Wallengren (BR. J. Dermatitis) in combination with WO 83/01252, WO 93/14084 individually or in combination (all are of record).

Wallengren (Contact dermatitis) teaches that the substance P antagonist Spantide diminishes the contact dermatitis caused by nickel sulfate (note the abstract and page 351).

Similarly, Wallengren (Br. J) teaches the inhibiting effect of substance P antagonists against various irritants (note abstract the entire article).

The teachings of WO 93 have been discussed above.

The WO 83 discloses the use of a peptide substance P antagonist in medicinal preparations including topical formulations (abstract, page 8 and claims).

In essence, these references teach implicitly that substance P has already been released in the host skin. It would thus, be obvious to one of ordinary skill in the art that application of an antagonist to already released substance P to nullify its effect.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant, based on the declaration submitted argues that both the Wallengren articles relate to an allergic skin condition such as contact dermatitis or

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irritant delayed reaction. These arguments are not persuasive since as pointed out above, the function of a substance P antagonist is to antagonize the action of released substance P and nullify its effects and it would have been obvious to one of ordinary skill in the art at the time the invention was made that it would nullify the effects of substance P irrespective of whether the substance P is released from a sensitive skin or allergic skin or skin in a inflammatory state. Furthermore, as pointed out in the previous action, instant claims recite even discomfort as one of the symptoms and applicant has not shown that the discomfort is not overcome by the treatment of substance P antagonist in the prior art.

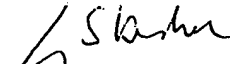
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
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GSK